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VIOXX, CELEBREX RAISE HEART ATTACK RISK, STUDIES SAY ;
MAKERS OF ARTHRITIS DRUGS DISPUTE RESEARCH FINDINGS, BUT
DOCTORS URGE CAUTION;
MANY CALL FOR MORE STUDY

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Body

The popular and heavily promoted new arthritis drugs Vioxx and Celebrex have been linked by researchers to a small but troubling increase in the risk of heart attacks and strokes.

Critics say the analysis is flawed and no cause for alarm.

Still, many agree the issue needs to be studied because millions of people take the drugs, known as cox-2 inhibitors.

The researchers analyzed four studies that were not designed to examine the drugs' effects on the heart. Until such research is done, doctors should use caution in prescribing them to patients with heart disease, said Dr. Eric Topol, co-author of the analysis and chairman of cardiovascular medicine at the Cleveland Clinic.

Topol said he uses such medication himself for knee arthritis, "but if I had known heart disease, I would be concerned."

The analysis, being published today in the Journal of the American Medical Association, includes a study that looked at the gastrointestinal side effects in 8,076 patients taking Vioxx or the pain reliever naproxen. Vioxx patients faced double the risk of serious cardiovascular problems, including strokes and heart attacks, though only 111 Vioxx patients had them. Two smaller Vioxx studies also suggested potential heart problems, Topol said.

Also, a study of 7,968 patients using Celebrex or two other pain relievers showed a slight but statistically insignificant increase in cardiovascular side effects with Celebrex, but the numbers were "trending in the wrong direction," Topol said.

An advisory panel warned the Food and Drug Administration in February of the Vioxx-naproxen study and said Vioxx should carry a warning label about potential cardiovascular risks. The FDA has yet to rule on that recommendation.

Cox-2 drugs are touted for their ability to relieve pain without the gastrointestinal upsets of aspirin and other medications and are among the most popular medicines worldwide. They are expected to generate \$6 billion in sales and 200 million prescriptions in the United States alone this year, Topol said. Celebrex and Vioxx are widely advertised on television and in magazines.

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Skeptics said the researchers presented incomplete and misleading data.

Merck & Co. and Pharmacia Corp., which make Vioxx and Celebrex respectively, disputed the analysis and said their drugs are safe.

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